DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 19, 2014

ROCHE DIAGNOSTICS
KELLI TURNER
REGULATORY AFFAIRS PRINCIPAL
9115 HAGUE ROAD, PO BOX 50416
INDIANAPOLIS IN 46250-0416

Re: K143342
Trade/Device Name: Elecsys T-Uptake CalSet
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: November 20, 2014
Received: November 21, 2014

Dear Ms. Kelli Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k143342

Device Name
Elecsys T-Uptake CalSet

Indications for Use *(Describe)*
T-Uptake CalSet is used for calibrating the quantitative Elecsys T-Uptake assay on the Elecsys and cobas e immunoassay analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary, Elecsys T-Uptake CalSet

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The purpose of this premarket notification is to obtain FDA review and clearance for the Elecsys T-Uptake CalSet.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road, P.O. Box 50416
Indianapolis, IN 46250-0416

Contact Person: Kelli Turner
Phone: 317-521-4515
Fax: 317-521-2324
Email: kelli.turner@roche.com

Secondary Contact: Michael Leuther
Phone: 317-521-3930
Fax: 317-521-2324
Email: michael.leuther@roche.com

Date Prepared: December 18, 2014

Device Name

Proprietary name:	Elecsys T-Uptake CalSet
Common name:	T-Uptake CalSet
Classification:	21 CFR 862.1150, Calibrator, Secondary
Product Code:	JIT

Establishment Registration

For the T-Uptake CalSet, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany, is 9610126 and for Penzberg, Germany, is 9610529. The establishment registration number for Roche Diagnostics United States is 1823260.

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510(k) Summary, Elecsys T-Uptake CalSet, *continued*

Classification FDA has classified the product as a Class II device.

Product Name	Panel	Product Code	Classification Name	Regulation Citation
Elecsys T-Uptake CalSet	Clinical Chemistry	JIT	Calibrator, Secondary	21 CFR 862.1150

Device Description

Elecsys T-Uptake CalSet:

- T-Uptake CalSet is a lyophilized buffer/protein/TBG matrix with added L-thyroxine. The Elecsys T-Uptake assay is traceable to a clinically defined human serum panel with a mean TBI (thyroxine-binding index) of 1.

Intended use

Elecsys T-Uptake CalSet:

- T-Uptake CalSet is used for calibrating the quantitative Elecsys T-Uptake assay on the Elecsys and **cobas e** immunoassay analyzers.

Predicate device

The Elecsys T-Uptake CalSet is substantially equivalent to the predicate device Elecsys T-Uptake CalSet (k961488).

Substantial Equivalence Comparison

The following tables compare the Elecsys T-Uptake CalSet with the predicate device.

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Comparison Table

The table below compares Elecsys T-Uptake CalSet with the predicate device, Elecsys T-Uptake CalSet (k961488).

The change in the new product was in the format, going from liquid to lyophilized.

Comparison Table

Characteristic	Elecsys T-Uptake CalSet (Candidate)	Elecsys T-Uptake CalSet (k961488)
Intended Use	T-Uptake CalSet is used for calibrating the quantitative Elecsys T-Uptake assay on the Elecsys and **cobas e** immunoassay analyzers.	Same.
Analyte	L-Thyroxine, syntheticThyroxine binding globuline (TBG), bovine	Same
Matrix	Buffer / protein (bovine serum albumin) / TBG matrix	Same
Levels	Two	Same
Target Ranges	Cal 1: 0.5 TBI conc. Cal 2: 1.3 TBI conc.	Cal 1: Same. Cal 2: Same.
Format	Lyophilized	Liquid, ready-for-use.
Stability	Unopened: • Store at 2-8°C until expiration date Opened: • 2-8°C: 84 days • -20°C: 84 days (freeze only once) Elecsys 2010 and **cobas e** 411 analyzers at 20-25°C: • up to 5 hours MODULAR ANALYTICS E170, **cobas e** 601 and **cobas e** 602: • use only once	Unopened: • Store at 2-8°C until expiration date Opened: • 2-8°C: 24 hours • 20-25°C: use only once • -20°C: 3 month

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Table *continued*

Characteristic	Elecsys T-Uptake CalSet (Candidate)	Elecsys T-Uptake CalSet (k961488)
Handling	Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the foam formation. Transfer the reconstituted calibrators into the supplied empty labeled snap-cap bottles . Elecsys 2010 and **cobas e** 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20‑25 °C. After use, close the bottles as soon as possible and store upright at 2‑8 °C. Due to possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed. If necessary, freeze in aliquots; see section on MODULAR ANALYTICS E170, **cobas e** 601 and **cobas e** 602 analyzers. MODULAR ANALYTICS E170, **cobas e** 601 and **cobas e** 602 analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the reconstituted calibrators into empty snap‑cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2‑8 °C or -20 °C for later use. Perform **only one** calibration procedure per aliquot. .	The calibrators are supplied ready for use in bottles compatible with the system. Elecsys 2010 and **cobas e** 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20-25°C. After use, close the bottles as soon as possible and store at 2-8°C. Due to possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed. MODULAR ANALYTICS E170, **cobas e** 601, **cobas e** 602 analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the ready for use calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8°C for later use. Perform only one calibration procedure per aliquot.
Traceability	Standardized using a clinically defined human serum panel with a mean TBI of 1.0.	Same

510(k) Summary, Elecsys T-Uptake CalSet, *continued*

Traceability	The T-Uptake CalSet has been standardized against a clinically defined human serum panel with a mean TBI of 1.
Evaluations Summary	The Elecsys T-Uptake CalSet was evaluated for value assignment, stability and reconstitution.
CalSet Value Assignment	Value assignment testing was conducted and passed pre-defined acceptance criteria. The target values for the two levels of the T-Uptake CalSet kit are chosen to obtain the best fit with the Reference Standard Curve. For each Elecsys T-Uptake CalSet lot manufactured, the calibrators are run in duplicate on at least three (3) Elecsys 2010 analyzers and at least three (3) MODULAR ANALYTICS E170 analyzers with all T-Uptake reagent lots available. The assigned value of each calibrator is defined as the median value obtained over at least six (6) runs on at least three (3) analyzers) of the respective calibrator. Measurement values for PreciControl Universal (Level 1 & 2) are read off from the calibration curves generated. The pre-defined acceptance criteria for PreciControl Universal have to be met to release the Assigned Values for T-Uptake CalSet.

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Stability Studies

Three studies were performed in order to verify the stability claims for the T-Uptake CalSet. Stability studies after reconstitution and an accelerated stability study were completed on the **cobas e** 411. Additionally, a real-time stability study is planned.

Study 1. Stability at 2-8°C, -20°C, in open vial and freeze/thaw cycles (after reconstitution):

The on-test and reference materials were tested in duplicate. The on-test material was reconstituted and stored in closed vials for 85 days at 2 to 8°C, for 699 days at -15 to -25°C and for 6 hours at 20 to 25°C in open vial. In addition, the stability of the T-Uptake CalSet for one (1) freeze/thaw cycles was evaluated.

The on-test signal recovery was calculated as percent of the reference value. The reference material was a freshly reconstituted set of T-Uptake CalSet.

T-Uptake CalSet was evaluated in duplicate on the **cobas e** 411. The acceptance criterion was 95 to 105 % signal recovery of the reference material value.

Study 2. Accelerated Stability:

The on-test material was stored lyophilized (as supplied to the user) at 35°C for 3 weeks. The reference material was a freshly reconstituted set of T-Uptake CalSet (stored at 2 to 8°C). After 3 weeks, the on-test and reference materials were tested in duplicate. The on-test recovery was calculated as a percent of the reference value.

One T-Uptake CalSet lot was evaluated in duplicate on the **cobas e** 411 analyzer.
The acceptance criterion was 95 to 105 % recovery of the reference material value.

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510(k) Summary, Elecsys T-Uptake CalSet, *continued*

Stability Studies, *continued*

Study 3. Real-Time Stability:

In addition, real-time stability is being evaluated as follows:
In the real-time stability study, the T-Uptake CalSet test material is stored at 2-8°C. The CalSets are tested in duplicate at specified intervals over the shelf life of the device up to the planned shelf life plus one month (25 months).

Real-time stability is calculated based on the recovery of signal of stressed calibrator (stored at 2-8°C) vs. unstressed calibrator (stored at -20°C). At the specified intervals over the shelf life, the mean value of the stressed calibrator was calculated as percent recovery of the unstressed value (each tested in duplicates at the same time point).

The acceptance criterion for T-Uptake Calibrator 1 and 2 is recovery of 95-105 % of the reference value.

Reconstitution Study

Reconstitution time for the lyophilized T-Uptake CalSet was tested. Two sets of T-Uptake CalSet were reconstituted, one for 15 minutes and the other for 30 minutes. Signal recovery after 30 minutes reconstitution was compared to the signal value after 15 minutes.

T-Uptake CalSet was evaluated in duplicate on the **cobas e** 411 analyzer as a reference.

The acceptance criterion was 95 to 105 % signal recovery of the reference material value.

Conclusion

We trust that the data and information provided in this Premarket Notification (510(k)) will support a determination of substantial equivalence for the Elecsys T-Uptake CalSet. The data supports a safe effective device which performs as well as or better than the predicate device.